

# ARTESTO (Abiraterone Acetate Tablets USP 250mg)

Abiraterone Acetate Tablet (250 mg)

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## What ARTESTO is used for

This medicine is used with prednisone or prednisolone for the treatment of prostate cancer that has spread to other parts of the body.

## How ARTESTO works

ARTESTO contains the active ingredient called abiraterone acetate. ARTESTO works by stopping the body from making testosterone; this can slow the growth of prostate cancer.

When ARTESTO is prescribed for the early stage of disease where it is still responding to hormone therapy, it is used with a treatment that lowers testosterone (androgen deprivation therapy).

When you take this medicine your doctor will also prescribe another medicine called prednisone or prednisolone. This is to lower your chances of getting high blood pressure, having too much water in your body (fluid retention), or having reduced levels of a mineral known as potassium in your blood.

## Before you use ARTESTO

- When you must not take it

Do not take this medicine if you have an allergy to:

- abiraterone acetate
- any of the other ingredients listed at the end of this leaflet

Do not take this medicine if you are a woman, especially if pregnant. ARTESTO is for use in male patients only.

Do not take this medicine if you have severe liver damage

Do not take this medicine in combination with Ra-223 (which is used to treat prostate cancer).

- Before you start to use it

Talk to your doctor before taking ARTESTO if you have:

- Liver problems
- High blood pressure or heart failure or low potassium (low blood potassium may increase risk of heart rhythm problems)
- Experienced heart or blood vessel problems.
- An irregular or rapid heart rate
- Shortness of breath
- Gained weight rapidly
- Swelling in the feet, ankles, or legs
- High blood sugar
- Taken ketoconazole in the past for prostate cancer

Talk to your doctor or pharmacist about the need to take this medicine with prednisone or prednisolone and the possible

effects on your bones before taking ARTESTO.

Decrease in red blood cells, reduced sex drive (libido), muscle weakness and/or muscle pain may occur.

ARTESTO contains sodium and lactose (a type of sugar). If you have been told by your doctor that you have an intolerance to some sugars, contact your doctor before taking this medicine.

This medicine also contains more than 1 mmol (or 27.2 mg) of sodium per dose of four tablets of 250mg. To be taken into consideration by patients on a controlled sodium diet.

ARTESTO must not be given in combination with Ra-223 due to a possible increase in the risk of bone fracture or death.

If you plan to take Ra-223 following treatment with ARTESTO and prednisone /prednisolone, you must wait 5 days before starting treatment with Ra-223.

If you are not sure if any of the above apply to you, talk to your doctor or pharmacist before taking this medicine.

## Blood monitoring

ARTESTO may affect your liver, and you may not have any symptoms. When you are taking this medicine, your doctor will check your blood periodically to look for any effects on your liver.

## Children and adolescents

This medicine is not for use in children and adolescents. If ARTESTO is accidentally ingested

by a child or adolescent, go to the hospital immediately and take the package leaflet with you to show to the emergency doctor.

#### Pregnancy and breast-feeding

ARTESTO is not for use in women. This medicine may cause harm to the unborn child if it is taken by women who are pregnant.

If you are having sex with a woman who can become pregnant, use a condom and another effective birth control method.

If you are having sex with a pregnant woman, use a condom to protect the unborn child.

#### - Taking other medicines

You need to take prednisone or prednisolone every day while you are taking ARTESTO.

The amount of prednisone or prednisolone you take may need to change if you have a medical emergency. Your doctor will tell you if you need to change the amount of prednisone or prednisolone you take.

Your doctor may also prescribe other medicines while you are taking ARTESTO and prednisone or prednisolone.

Tell your doctor or pharmacist if you are taking, have recently taken or might take any other medicines listed below. This is important because ARTESTO may increase the effects of a number of medicines including some medicines for diabetes. Your doctor may want to change the dose of these medicines.

- Phenytoin, carbamazepine, rifampicin, phenobarbital, St John's wort
- Metoprolol, propranolol, haloperidol, venlafaxine

- Pioglitazone, repaglinide
- Quinidine, disopyramide, amiodarone, methadone
- Spironolactone

#### **How to use ARTESTO**

Always take this medicine exactly as your doctor has told you. Check with your doctor or pharmacist if you are not sure.

#### - How much to use

The recommended dose is 1,000 mg (four tablets) once a day.

#### - When to use it

Take this medicine by mouth and swallow the tablet whole with water. Do not chew, break or split the tablet.

Take ARTESTO at least one hour before or at least two hours after eating. Do not take ARTESTO with food.

ARTESTO is taken with a medicine called prednisone or prednisolone. Take the prednisone or prednisolone exactly as your doctor has told you.

#### - How long to use it

Do not stop any treatment unless your doctor tells you to do so.

#### - If you forget to use it

If you forget to take ARTESTO or prednisone or prednisolone, take your usual dose the following day.

If you forget to take ARTESTO or prednisone or prednisolone for more than one day, talk to your doctor without delay.

#### - If you use too much (overdose)

If you take more than you should, talk to your doctor or go to a hospital immediately.

#### **While you are using it**

#### - Things you must do

Tell your doctor if you have been told you have any heart or blood vessel conditions, including heart rhythm problems (arrhythmia), or are being treated with medicines for these conditions.

Tell your doctor if you have:

- Yellowing of the skin or eyes
- Darkening of the urine
- Severe nausea or vomiting

These could be signs or symptoms of liver problems. Rarely, failure of the liver to function (called acute liver failure) may occur, which can lead to death.

Be sure to keep all your doctor's appointments so your progress can be checked.

Your doctor will want to do some blood and other tests from time to time to check on your progress.

Be sure to follow up your doctor's instructions about other medicines you should take, and other things you should do.

#### - Things you must not do

This medicine must not be taken with food. Taking ARTESTO with food may cause side effects. Do not stop taking ARTESTO or prednisone or prednisolone unless your doctor tells you to.

If you have any further questions on the use of this medicine, ask your doctor or pharmacist.

- Things to be careful of

This medicine is not likely to affect your ability to drive and use any tools or machines.

**Side effects**

Like all medicines, ARTESTO can cause side effects, although not everybody gets them.

Stop taking ARTESTO and see a doctor immediately if you notice any of the following:

- Muscle weakness, muscle twitches or a pounding heart beat (palpitations). These may be signs that the level of potassium in your blood is low.

Other side effects include:

Very common:

- Fluid in your legs or feet, low blood potassium, liver function test increases, high blood pressure, urinary tract infection, diarrhoea.

Common:

- High fat levels in your blood, chest pain, irregular heart beat (atrial fibrillation), heart failure, rapid heart rate, severe infections called sepsis, bone fractures, indigestion and blood in urine, rash.

Uncommon :

- Adrenal gland problems (related to salt and water problems), abnormal heart rhythm (arrhythmia), muscle weakness and/or muscle pain.

Rare :

- Lung irritation (also called allergic alveolitis). Failure of the liver to function (also called acute liver failure).

Not known :

- Heart attack, changes in ECG – electrocardiogram (QT

prolongation).

Bone loss may occur in men treated for prostate cancer. ARTESTO in combination with prednisone or prednisolone may increase bone loss.

You may report any side effects or adverse drug reactions directly to the National Centre for Adverse Drug Reaction Monitoring by visiting the website <http://nptra.gov.my> [Consumers → Reporting side effects to medicines (ConSERF) or Vaccines (AEFI)].

**Storage and disposal of ARTESTO**

- Storage

Store below 30°C. Store in the original container.

Keep this medicine out of the sight and reach of children.

Do not use this medicine after the expiry date which is stated on the carton, and bottle. The expiry date refers to the last day of that month.

This medicine does not require any special storage conditions.

- Disposal

Do not dispose any medicines via wastewater or household waste. Ask your pharmacist how to dispose medicines you no longer use. These measures will help to protect the environment.

**Product Description**

- What it looks like

ARTESTO tablets are white to off-white, oval shaped tablets

debossed with “NA250” on one side and plain on other side.

- Ingredients

Active ingredient

- Each tablet contains 250mg Abiraterone acetate.

Inactive ingredients:

- Lactose Monohydrate
- Microcrystalline Cellulose
- Croscarmellose Sodium
- Sodium Lauryl Sulphate
- Povidone (K-30)
- Colloidal Silicon Dioxide
- Magnesium Stearate

- MAL number

MAL21116026ACZ

**Manufacturer:**

Natco Pharma Limited (Pharma Division), Kothur – 509228, Rangareddy District, Telangana, India

**Product Registration Holder**

DUOPHARMA HAPI SDN BHD  
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03 June 2026

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